

K964379

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
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Contact: Kevin Kennan
Regulatory Affairs Specialist

Device Identification: Common Name:
Cannula

Trade Name: (optional)
KSEA Puncture Cannula

Indication: The KSEA Puncture Cannula are intended for use by qualified surgeons or physicians to puncture and drain a cyst or other structure within the surgical site.

Device Description: The KSEA Puncture Cannula are manual reusable surgical devices provided to the end-user in a non-sterile condition. The KSEA Puncture Cannula are part of the KSEA "Irrigation and Suction System" and are intended to be used with KSEA Irrigation and Suction System Handpiece. The body contact materials are surgical grade stainless steel.

Substantial Equivalence: The KSEA Puncture Cannula for the puncture and evacuation of cysts are substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the KSEA Puncture Cannula and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed: 

Kevin Kennan
Regulatory Affairs Specialist